Cyfluthrin S.F.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 5 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP Nos. 4F4313/4H5687. Cyfluthrin on Citrus Agricultural Commodities/Food and Feed Processed Commodities. Review of Residue Data and Analytical Methodology. MRID No. 430765-02. DP Nos. 200053, 200059. CB Nos. 13304, 13305.

FROM: Stephanie H. Willett, Chemist SHW
Tolerance Petition Section 2
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

THRU: Richard Loranger, PhD, Acting Chief R. Loranger
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

TO: George LaRocca/Adam Heyward, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

Miles, Incorporated is requesting the establishment of tolerances for cyfluthrin ([cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] on citrus fruits, oil, dried pulp, and molasses at 0.2, 1.0, 1.0, and 0.5 ppm, respectively, in the subject petitions. Tolerances for cyfluthrin have previously been established on several commodities at levels ranging from 0.01 to 4 ppm, and are listed in 40 CFR 180.436. Food and feed additive tolerances of 0.05 ppm have also been established as a result of use of cyfluthrin in food/feed handling establishments and are listed in 40 CFR 185.1250 and 186.1250, respectively.

Cyfluthrin is not a reregistration chemical, and therefore is not subject to reregistration review of the current database.

Conclusions

1. All product chemistry data requirements for technical grade cyfluthrin and BAYTHROID^{R}2 have been addressed. No impurities are expected to be present in the TGAI which would cause residue chemistry concerns. All inerts in the end use product have been cleared for agricultural use.

2a. The proposed label/section B is unacceptable. The treatment rate specified on the label and the treatment rates in the field trials are different, and thus the proposed use is not adequately supported (cf. 0.1 lb ai/A and 1 oz ai/A; see also conclusion 5a and discussion under Residue Data Section).

2b. The Section B/label must be modified to specify a minimum spray volume.

2c. CBTS typically only approves regional registration requests for minor crops with low dietary intake, and this is not the case with citrus fruits. However, as a result of the 1990 Farm Bill the requirements for regional registrations were expanded to include economic considerations (see 7/7/93 memo of Anne Lindsay re: Policy for Regional Registrations). The present practice within CBTS is to defer to BEAD to make a determination as to whether or not the proposed use can be considered a minor use based on economic considerations. The product manager should go through the appropriate administrative procedures to obtain a formal response from BEAD on this matter.

3. The nature of the residue in plants and animals is adequately understood. The residue to be regulated is parent cyfluthrin.

4. Adequate analytical methods are available for the enforcement of tolerances in plant and animal commodities. These methods have been forwarded to FDA for inclusion in PAM II. The limit of quantitation is as low as 0.01 ppm. Cyfluthrin can also be recovered using FDA multiresidue methodology.

5a. The application rates used in the field trials were lower than the proposed label rate. The petitioner will either need to reduce the label/section B rate to the rates used in the trials (0.4 to 1.0 oz ai/acre), or conduct additional field trials at the higher label rate of 1.6 oz ai/A, equivalent to 0.1 lb ai/A. Regardless of the application rate, additional field trial data may be required if it is determined that a regional registration on citrus is not practical (see conclusion 2c, and discussion under **Proposed Use** section). If it is determined that a regional registration is not appropriate, the registrant should consult EPA Publication No. EPA 738-K-94-001 entitled Pesticide Reregistration Rejection Rate Analysis Residue Chemistry: Follow-up Guidance (June 1994) for the latest guidance on the conducting field trials.

5b. The citrus processing study data are adequate since quantifiable residues were present in the processed raw agricultural commodities. Food/feed additive tolerances will be needed for oil, molasses and dried pulp (see discussion under Residue Data).

6. CBTS will withhold its conclusions regarding the adequacy of meat and milk tolerances until the appropriate tolerance levels for citrus and its feed processed commodities can be determined. This can only be done after the deficiencies concerning the residue data and the proposed use have been addressed.

Recommendations

CBTS recommends against the proposed tolerances for cyfluthrin on citrus and its processed food and feed products at this time. The deficiencies outlined above in conclusions 2a, 2b, 2c, and 5a must be resolved for reconsideration of this request for tolerances.

Note to PM: CBTS is deferring to BEAD on the economic validity of the requested regional registration for cyfluthrin on citrus. The product manager should go through the appropriate administrative procedures to obtain a formal response from BEAD on this matter.

Detailed Considerations

Product Chemistry

The manufacturing process of technical grade cyfluthrin has been previously described and found to be acceptable (see PP No. 4F3046, 5/18/84 memo of K. Arne). None of the actual or theoretical impurities are expected to cause residue concerns.

The end use product proposed for use on citrus is Baythroid^{R} 2 Emulsifiable Pyrethroid Insecticide (EPA Reg. No. 3125-351), which contain 25% cyfluthrin (w/w). Since the product has already been registered, it is assumed that all inerts have been cleared by RD for use in agricultural pesticides.

Proposed Use

To control citrus thrips only in the states of California and Arizona, a single application of 6.4 fluid ounces per acre (0.1 lb ai/acre) is specified. Application is by use of ground equipment only, in sufficient water for complete coverage of foliage. A single application may be made per crop season. Application soon after pollination is most effective in preventing thrips scarring. Applications may be made up to the day of harvest (0 day PHI).

The proposed label/section B is unacceptable. The treatment rate specified on the label and the treatment rate in the field trials are different, and thus the proposed use is not adequately

supported (cf. 0.1 lb ai/A and 1 oz ai/A; see also Residue Data Section). Also, the label must specify a minimum spray volume. Guidance for determining an appropriate spray volume is attached to the memo (see attachment 1).

CBTS typically only approves regional registration requests for minor crops with low dietary intake, and this is not the case with citrus fruits. However, as a result of the 1990 Farm Bill the requirements for regional registrations were expanded to include economic considerations (see 7/7/93 memo of Anne Lindsay re: Policy for Regional Registrations). The present practice within CBTS is to defer to BEAD to make a determination as to whether or not the proposed use can be considered a minor use based on economic considerations. The product manager should go through the appropriate administrative procedures to obtain a formal response from BEAD on this matter.

Nature of the Residue

The nature of the residue in plants is presently considered to be adequately understood. Studies have previously been conducted to delineate the metabolism of radiolabeled cyfluthrin in cotton and soybeans (PP No. 3G2976), potatoes (PP No. 4F3046), apples (PP No. 4F3046), wheat and tomatoes (PP No. 9F3731). All studies were considered to be acceptable, and produced similar results. The major terminal residue was cyfluthrin, which was shown to metabolize slowly. The residue to be regulated is parent cyfluthrin.

The nature of the residue in ruminants is also considered to be adequately understood. When a dairy cow was dosed with radiolabeled cyfluthrin at 33 ppm for five consecutive days, parent cyfluthrin constituted the major terminal residue in various tissues and milk.

Citrus commodities are not poultry feed items. Therefore, the metabolism of cyfluthrin in poultry is irrelevant to this petition. Similarly, citrus fruits are orchard crops, and therefore rotational crop study data requirements do not apply to this petition.

Analytical Methodology

Analytical methodology suitable for the enforcement of cyfluthrin tolerances in plant and animal commodities is available. The methodology was successfully validated by EPA's Beltsville lab in support of tolerances on cottonseed (see PP No. 4F3046). For crops the sample is ground and extracted with organic solvents, and cleaned up using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture

detector. For meat, milk and eggs, the methodology also involves extraction with organic solvents and additional partitioning with various solvents to remove polar and nonpolar interferences, followed by final cleanup using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture detector. Limits of quantification are as low as 0.01 ppm, but vary according to the commodity (see also 5/5/94 memo of J. Morales, PP No. 3F4204). The methods were forwarded to FDA for inclusion in PAM II in March 1988, but have not yet been published.

Cyfluthrin has also been analyzed using the FDA multiresidue protocols. According to the FDA Pesttrack database, it can be completely (>80%) recovered using protocol A (see also 12/4/87 memo of M. Bradley, PP No. 4F3046).

Magnitude of the Residue: Field Trial Data
(MRID No. 430765-02)

Data from trials conducted in California (4) and Arizona (3) were submitted in support of the citrus tolerance. The citrus types were as follows: oranges, 3; grapefruit, 2; and lemons, 2. **Different spray volumes were used which resulted in application rates on a per acre basis of 0.37 to 1 oz ai/acre (equivalent to 0.3 to 0.6 times the maximum proposed label rate)**. Applications were made so that the same amount of pesticide was applied to each tree. This amounted to 0.45 to 0.5 ml of formulation per gallon of applied spray. Mature fruit was harvested at 0, 3, 7, 13-14 and 28-31 days after application. Samples were taken from the four quarters of each tree, high and low portions and portions exposed and sheltered from foliage. After harvest, samples were maintained frozen until shipped to Miles Research for analysis. Samples of oranges, grapefruits and lemons (as well as the orange processing samples) were held in storage for a maximum period of 199 days. Storage stability data were recently reviewed which indicates that cyfluthrin is stable under frozen conditions in oranges, juice and dry pulp for up to 7 months (see 5/5/94 memo of J. Morales).

Whole fruit samples were homogenized, and residue levels determined using a slightly modified version of method No. 85823, which is the enforcement methodology described above. Modifications included variations of extraction solvents (from 4:1 methanol:water to 2:1 acetone:chloroform), alumina column cleanup instead of florisil column clean up for grapefruit and lemons, and use of a capillary column in the GC analysis which provided better separation than the packed columns used in the original method. To validate the results of the analyses of the various citrus fruits, control orange samples were fortified at 0.01 ppm (2 replicates), 0.02 ppm, and 0.05 ppm. Recoveries ranged from 92 to 110%. Concurrent recovery samples in oranges, grapefruit, and lemons were run with each treated sample set. These recoveries ranged from 68% to 123%.

In addition, a blind check sample from one of the experimental treatments was analyzed at Miles Research and Ricerca where the processing study samples were analyzed (see discussion below). Both labs determined the residue level to be 0.02 ppm in the blind sample. The chromatographic response was shown to be linear over an appropriate range. The limit of determination was 0.01 ppm.

A summary of the residue data provided in support of the proposed 0.2 ppm on citrus fruit is given in the table that follows.

TABLE 1: SUMMARY OF CYFLUTHRIN RESIDUES IN FIELD TREATED CITRUS

RAC TREATED	LOCATION	PHI (DAYS)	APPLICATION RATE OZ AI/100 GALLONS OZ AI/ACRE	TOTAL GROSS RESIDUE (PPM)
Grapefruit	California	0 3 7 14 31	0.4 oz ai/100 gal 0.37 oz ai/acre	0.02 0.01 <0.01 <0.01 <0.01
Grapefruit	Arizona	0 3 7 14 30	0.4 oz ai/100 gal 0.72 oz ai/acre	<0.01 <0.01 0.02 0.02 0.02
Lemons	California	0 3 7 14 31	0.4 oz ai/100 gal 0.37 oz ai/acre	0.06 0.04 0.03 0.01 0.02
Lemons	Arizona	0 3 7 14 28	0.4 oz ai/100 gal 1.0 oz ai/acre	0.04 0.02 0.03 0.01 0.02
Oranges	California	0 3 7 14 31	0.4 oz ai/100 gal 0.37 oz ai/acre	0.02 <0.01 <0.01 <0.01 <0.01
Oranges	California	0 3 7 13	1.4 oz ai/100 gal 1.0 oz ai/acre	0.20 0.10 0.08 0.07
Oranges	Arizona	0 3 7 14 30	0.4 oz ai/100 gal 0.30 oz ai/acre	<0.01 0.01 0.01 <0.01 <0.01

Processing Study Data

A separate field trial was conducted in Florida for the purpose of determining whether or not residues of cyfluthrin concentrated in citrus processed commodities. Cyfluthrin was applied to an experimental plot of orange trees at a rate of 5 oz ai/acre (3 times maximum proposed label rate). Representative orange samples were harvested 14 days after treatment. Samples were shipped to University of Florida Citrus Research Center and processed using a small scale apparatus according to typical practices to dried pulp, peel, oil, molasses and juice (details included). After processing, the samples were stored frozen until analyzed (≤ 199 days). Residues were determined using methodology previously described. In addition to the validation data previously described, concurrent recoveries of control samples fortified at levels of 0.10 to 4 ppm of the processed commodities were analyzed along with each analysis set. Recoveries at these levels ranged from 74 to 123%.

The gross residue levels were reported as follows:

TABLE 2. SUMMARY OF ORANGE PROCESSING DATA

Orange Commodity	Gross Residue ppm	Concentration Factor	Proposed Food/Feed Additive Tolerance
RAC	0.20	---	---
Dried Pulp	1.05	5.3	1.0
Peel	0.23	1.2	0.5
Oil	1.06	5.3	1.0
Molasses	0.58	2.9	0.5
Juice	<0.01	<1.0	---

Sample calculations, raw data and chromatograms were provided in support of the residue field trial and processing study data.

CBTS Conclusions

The residue field trial data are deficient. First, as previously mentioned, the proposed label application rate and the application rates used in the field trials are incompatible. The application rates used in the field trials were lower than the proposed label rate. The petitioner will either need to reduce the label/section B (0.4 to 1.0 oz ai/acre), or conduct additional field trials at the higher rate of 1.6 oz ai/A (0.1 lb ai/A). Regardless of the application rate, additional field trial data may be required if it

is determined that a regional registration on citrus is not practical (see previous discussion under **Proposed Use** section). If it is determined that a regional registration is not practical, the registrant should consult our latest guidance document entitled Pesticide Reregistration Rejection Rate Analysis Residue Chemistry: Follow-up Guidance (June 1994, Document No. EPA 738-K-94-001) concerning the suggested number and location of field trials for citrus, which become applicable in 1995.

The citrus processing study data are adequate since quantifiable residues were present in the processed raw agricultural commodities. Food/feed additive tolerances will be needed for molasses, oil and dried pulp. The processed commodities for citrus are wet pulp, dried pulp, molasses, oil, and juice (see June 1994 Guidance Document). No data were specifically supplied for wet citrus pulp. However, cultural practice information on the citrus processing industry indicates that citrus peel is often the same as wet citrus pulp. We can therefore assume that based on the processing data provided there is not significant concentration from the citrus RAC to wet pulp, and therefore no feed additive tolerance is required (0.2 ppm x 1.2 = 0.24 ppm). We note also that a worst case estimate of secondary residues in meat and milk will result from assuming the presence of dried pulp in the cattle diet.

Secondary Residues in Meat, Milk and Eggs

Citrus molasses, dried pulp and wet pulp may comprise up to 15, 20 and 30%, respectively, of a cattle diet. A 0.01 ppm tolerance for milk and a 0.05 ppm tolerance for meat, fat and meat byproducts have already been established for cyfluthrin as a result of previously registered agricultural uses. CBTS will withhold its conclusions regarding the adequacy of these tolerances until the appropriate tolerance levels for citrus and its feed processed commodities can be determined. This can only be done after the deficiencies concerning the residue data and the proposed use have been addressed.

attachment: Guidance for Orchard Spray Application (4 pages)

cc: RF, PP No. 4F4313/4H5687, S. Willett, E. Haeberer, Cir, Subject File

CM2:305-6380:RM 804C:7509C:SHWillett:shw-12/01/94
RDI: E. Haeberer, 11/30/94; M. Flood, 12/2/94; R. Loranger, 12/5/94

Attachment

Page 1 of 4

Guidance for Orchard Spray Application

As a guidance to any future orchard spray applications, the petitioner should incorporate one or more of the following concepts in their submissions as the means of instructing the users on how to vary the quantity of a.i./acre that is needed for different tree sizes.

Procedure 1. For High Volume (HV) Spray Applications to Orchards

Determine volume/A to spray orchard to run-off. Use so much active ingredient/ 100 gal and multiply this number by the volume/A to spray your orchard to runoff to determine the amount of active ingredient/A.

For Example:

Step 1: Use rate (determined by petitioner).....0.5 lb act/100 gal.

Step 2: To spray one acre of your orchard to run-off...300 gal/A.

Step 3: The amount of lb a.i./acre in 300 gal of water is 1.5 lb (0.5 lb act/100 gal x 300 gal/A).

Procedure 2. Estimation of Tree Row Volume (TRV) to Calculate the Gallons/A Needed to Spray to Run-off

Step 1: 43,560/between-row spacing (ft) = feet of row/acre.

Step 2: Feet of row/acre x tree height (ft) x cross-row limb spread (ft) = cu ft of TRV/acre.

Step 3: Select one of the following numbers that best indicate the canopy density of each separate orchard or block:

0.70 gal/1,000 cu ft: Trees extremely open, light visible through entire tree, less than 15 scaffold limbs/tree or young tree.

0.75 gal/1,000 cu ft: Trees very open, 18 - 21 scaffold limbs/tree, light penetration throughout tree, healthy spurs within tree canopy.

(247)

Attachment

0.80 gal/1,000 cu ft: Trees well pruned, adequate light in trees for healthy spurs throughout trunk and scaffold limbs, many holes in foliage where light can be seen through tree.

0.85 gal/1,000 cu ft: Trees moderately well pruned, reasonable spur population within canopy, tree thick enough that light cannot be seen through bottom two-thirds of tree.

0.90 gal/1,000 cu ft: Trees pruned minimally, spurs inside canopy are weak due to limited light, very few holes where light can be seen through the tree.

0.95 gal/1,000 cu ft: Little or no pruning, spurs dead or very weak in canopy, very little light visible through tree.

1.00 gal/1,000 cu ft: Tree totally unpruned, extremely thick, no light visible anywhere through tree canopy, trees more than 20 ft high.

Step 4: $$\frac{\text{cu ft of TRV/acre (from Step 2)} \times \text{density (from Step 3)}}{1{,}000}$$

= gal of dilute solution to be applied/A.

Step 5: Using the volume of spray to run-off calculated in Step 4 above, calculate the lb a.i./acre using the formula of Procedure 1 (Step 3).

For Example: An orchard has rows spaced 25 ft apart, tree height is 20 ft, and cross row limb spread is 17 ft. The tree density is 0.85.

Step 1: $43{,}560 \text{ ft}^2/25 \text{ ft} = 1{,}742.4 \text{ ft}$

Step 2: $1{,}724.4 \text{ ft} \times 20 \text{ ft} \times 17 \text{ ft} = 592.416 \text{ cu ft}$

Step 3: Density has been given as 0.85

scaffold limbs/tree or young tree.

Step 4: $(592.416 \times 0.85)/1{,}000 = 503.5$ gal/acre

Attachment

Step 5: Using the volume of spray to run-off calculated in Step 4 above, calculate the lb a.i./acre using the formula of Procedure 1 (Step 3).

Procedure 3. Estimation of Gallons of Pesticide Spray Solution per acre to Spray to Run-off or LV Application at the Full Leaf Stage of Canopy Using the following Table

Approximate number of gallons of pesticide spray liquid needed per acre for coverage at the full leaf stage of canopy development in tree fruit orchards using high volume (HV) dilute sprays and low volume (LV) concentrate sprays applied with airblast sprayers

Tree height (ft) X Tree width (ft)[b]	Spray Type	Gallons Per Acre[a] distance between tree rows (ft)												
		16	18	20	22	24	26	28	30	32	34	36	38	40
80	HV	152	136											
	LV	20[c]	17[c]											
100	HV	191	169	152										
	LV	25	22[c]	20[c]										
150	HV	256	254	229	208	191								
	LV	37	33	29	27	25								
200	HV	...[d]	...	305	277	254	235	218						
	LV	...	...	39	36	33	30	28						
250	HV	...	...	...	346	317	293	272	254	238				
	LV	...	...	...	45	41	38	35	33	31				
300	HV	...	...	...	416	381	352	327	305	286	269	254	241	229
	LV	...	...	...	53	49	45	42	39	37	35	33	31	29
350	HV	...	...	...	...	445	411	381	356	334	314	296	281	267
	LV	...	...	...	...	57	53	49	46	43	40	38	36	34
400	HV	...	...	...	...	...	469	436	407	381	359	339	321	305
	LV	...	...	...	...	...	60	56	52	49	46	44	41	39
450	HV	...	...	...	...	...	...	490	457	429	404	381	361	343
	LV	...	...	...	...	...	...	63	59	55	52	49	46	44
500	HV	...	...	...	...	...	...	...	508	476	448	424	401	381
	LV	...	...	...	...	...	...	...	65	61	58	54	52	49
550	HV	...	...	...	...	...	...	...	...	524	493	466	441	419
	LV	...	...	...	...	...	...	...	...	67	63	60	57	54
600	HV	...	...	...	...	...	...	...	...	...	538	508	481	457
	LV	...	...	...	...	...	...	...	...	...	69	65	62	59

[a] See text for full details of calculation. All values rounded to the nearest whole gallon. Based on standard dosage volumes of 0.7 gallon per 1,000 cu ft TRV for HV and 0.09 gallon for LV sprays. Trees which have a very dense foliar canopy may require slightly more spray volume than shown.

[b] Where small trees are interplanted with large trees in the same row, use only the large tree dimensions.

[c] LV applications of less than 25 gallons per acre are not generally recommended because of other factors affecting coverage.

[d] Data not given because the combination of this tree size on this planting density is unlikely.

References: Unrath, C. R., and T. B. Sutton. North Carolina State University, Raleigh, NC 27695. Bulletin AG 37.

Attachment

The amount of a.i./acre can be calculated by using the volume of spray to run-off per acre found in the table above into the formula used in Procedure 1 (Step 3) above.

Procedure 4. For Low Volume (LV) and Ultra-low Volume (ULV) Applications to Orchards

Take the amount of a.i./A for orchard calculated from Procedure 1; the TRV estimated from Procedure 2; or the full leaf stage of canopy table from Procedure 3; and add to X gal of water/A for LV applications or Y gal of water and/or other solvent/A. X and/or Y is (are) determined by the petitioner to coincide with the proposed use. Less active ingredient/A is normally required for LV and ULV applications. The lower amount of active ingredient/A, if proposed, should be stated as a fraction of the high volume rate. Residue data must be submitted for all uses proposed on the label. Therefore, LV and/or ULV applications will not be allowed if residue data have been submitted for HV applications only.